IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE DIGITEK®
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

THE ACTAVIS DEFENDANTS' BRIEF OPPOSING PLAINTIFFS' MOTION TO COMPEL DOCUMENTS AND DEPOSITION TESTIMONY

I. INTRODUCTION AND SUMMARY OF ACTAVIS' RESPONSE

Plaintiffs' Motion to Compel seeks a report prepared by, and deposition testimony from, Mr. Paul Galea regarding his alleged seven-month audit of Actavis Totowa LLC facilities to determine whether Actavis Totowa was in compliance with federal Good Manufacturing Practices ("GMPs"). But there was no such seven month audit to determine GMP compliance at the Actavis Totowa facility, and there is no GMP compliance report to produce. To the contrary, Mr. Galea prepared an assessment report of Actavis Totowa operations to assist him in harmonizing the GMP aspect of Actavis entities globally; he did not conduct a routine GMP compliance audit of Actavis Totowa operations. Because Plaintiffs' motion is based entirely on this mischaracterization of Mr. Galea's testimony, their arguments lack merit and the motion should be denied.

Specifically, Actavis did not waive the self-critical analysis privilege as to Mr. Galea's assessment report because it is non-responsive to Plaintiffs' June 2009 document requests. Moreover, defense counsel was not aware of Mr. Galea's 2007 work at the Actavis Totowa facility or his report until shortly before his December 9, 2009 deposition. And, the parties'

agreed upon culling and search terms did not capture the assessment report at issue because the report is non-responsive to those search terms.

Nor may Mr. Galea's work at Actavis Totowa (assessment and harmonization) be characterized as a "routine and voluntary" safety audit to "fit" the legal issue before the Court into inapposite case law. When presented fully and accurately, there is no question that Mr. Galea's work and report are of the type that fall squarely into the self-critical analysis privilege as defined and applied in this Circuit.

But even so, and contrary to plaintiff's argument, the report and testimony sought are entirely irrelevant to the shifting theories in this litigation. Mr. Galea's work and report pre-date and have nothing to do with Plaintiffs' first theory – double-thick Digitek® tablets or the recall; and they have nothing to do with Plaintiffs' second theory – inconsistent (high or low) digoxin dosages in distributed Digitek®. Plaintiffs' last ditch theory is simply an expansive search to discover any information that might establish that the newly-acquired Actavis Totowa facility was not in compliance with good manufacturing practices in 2007. This latest theory is yet another attempt to push the scope of discovery in this litigation far beyond distributed Digitek® tablets to manufacturing practices in general, contrary to PTO Nos. 27 and 37. But even so, and aside from how this third theory possibly assists plaintiffs in establishing a specific defect in distributed Digitek® tablets beyond sheer speculation, Mr. Galea's work and report do not constitute a "Good Manufacturing Practice compliance audit[]." (Pls.' Mot. at 1.) For these reasons, Plaintiffs' Motion to Compel should be denied.

II. COUNTERSTATEMENT OF THE FACTS

Mr. Galea is the Director of Quality Assurance operations at Actavis Totowa LLC. (Affidavit of Paul Galea ("Galea Aff.") at ¶ 1, attached as Exh. A.) He became an Actavis Totowa employee in October 2007, having worked the previous three years as the Assistant

Quality Assurance Manager for Actavis Ltd. facilities in Malta. (Deposition testimony of Paul Galea ("Galea Dep."), taken December 9, 2009, at 11-12, 18, 157, excerpts attached hereto as Exh. B.) Actavis Ltd. is a subsidiary of Actavis Group. (Galea Dep. at 12.)

At the end of 2006, Actavis Group asked Mr. Galea to travel to the United States to 1) conduct a general assessment of the recently-acquired Actavis Totowa LLC entity from a GMP perspective so that 2) he could harmonize aspects of Actavis Totowa GMP operations with GMP operations of other divisions and operating entities within Actavis on a global basis. (*Id*. at 19; *see also* Galea Aff. at ¶ 6.) Mr. Galea defined good manufacturing practices as "a set of rules and guidances which direct you in the manufacturing and packaging and testing of your product" to ensure product safety. (*Id*. at 167-168.) The goal of harmonization is to "look at the various companies and see that they are working under the same umbrella. When you have a big corporation, it's something that you typically would like to do . . . I would say it's more how to streamline operations within the various countries to look as similar as possible." (*Id*. at 47-48.)

While Mr. Galea testified that, generally speaking, it is a routine part of a company's business to do GMP compliance assessments (*id*. at 190), he did not conduct a GMP compliance audit of the Actavis Totowa facility; such an audit was not included in the scope of his assignment. (Galea Aff. at ¶ 7). When pressed as to whether Actavis Totowa had any major or minor GMP issues, Mr. Galea made clear that his job was not to determine whether any GMP issues were minor or major – that "was not really the scope of my assessment." (*Id*. at 20.) Rather, the true nature of his work at Actavis Totowa was more of a "general assessment . . . which you would typically do when you're visiting for a short period of time." (*Id*. at 24-25.)[1]

[1] In fact, in his quest to establish that Actavis Totowa needed a "Quality System Improvement Plan" in 2007 to address quality problems, as opposed to improving quality systems, Plaintiffs' counsel went so far as to ask Mr. Galea if he had "ever heard of the phrase 'if it ain't broke,

Mr. Galea made five trips to the Actavis Totowa facility in 2007 to complete his assignment. (*Id*. at 30-31.) His "general assessment" of the Actavis Totowa facility took place over the course of one week in February 2007, and the very beginning of a subsequent March 2007 visit. (*Id*. at 30, 41.) Following his week-long assessment in February 2007, and before he returned in March 2007, he sent a report of his assessment to an individual in the Quality Systems Department at Actavis Group. (*Id*. at 35.) That report constitutes Mr. Galea's observations and mental impressions of various aspects of Actavis Totowa operations from a GMP perspective. (Galea Aff. at ¶ 4.) The remaining portion of Mr. Galea's March 2007 visit, and his subsequent trips to Actavis Totowa in May, June/July, and August 2007, concerned global GMP "harmonization." (*Id*. at 40-41.)

Defense counsel did in fact object to questions during Mr. Galea's deposition seeking information regarding his observations and mental impressions. But contrary to Plaintiffs' representations (Pls.' Mot. at 4), at no time did defense counsel instruct Mr. Galea not to testify about the objective facts underlying his assessment. In fact, he instructed just the opposite. (*See, e.g*., Galea Dep. 24, instructing Mr. Galea to answer as to what he physically reviewed and inspected, but not to answer as to his substantive evaluations.)

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don't fix it'"? (Galea Dep. at 180.) But this question reflects a fundamental misunderstanding of a pharmaceutical company's ever-evolving practice of improving quality systems and good manufacturing practices. To suggest that a pharmaceutical company would sit back idly until something "breaks" is counterintuitive and flat-out wrong. This is yet another example of Plaintiffs' far-reaching fishing expedition for anything they can unearth regarding GMP problems at Actavis Totowa before the Digitek® recall.

III. LAW AND ARGUMENT

A. Actavis Did Not Waive the Self-Critical Analysis Privilege as to Mr. Galea's Deposition Testimony or the General Assessment Report He Submitted to Actavis Group in Early 2007.

Though Plaintiffs represent otherwise, it is plain from the deposition testimony set forth above that Mr. Galea did *not* perform a seven-month audit to determine whether Actavis Totowa was in compliance with federally-mandated GMPs. (Pls.' Mot. at 9, 14.) Nor does any report exist concerning a seven-month audit of Actavis Totowa GMP compliance. And as for Plaintiffs' July 2009 document requests, Mr. Galea's general assessment report does not constitute: 1) an "internal investigation[] conducted in the last ten years involving or relating to Digitek® or any of its component parts or raw materials" (Doc. Req. 74); 2) a specific "internal audit conducted by [a] compliance division or [] quality department" (Doc. Req. 75); 3) an "inspection" conducted by an Actavis compliance inspection group (Doc. Req. 76); or 4) the outlining of "procedures related to internal audits conducted by the compliance division or any quality department in the last ten years." (Doc. Req. 77; *see* Pls.' Statement Pursuant to U.S.D.C., S.D. W. Va. L. R. 37.1(c).)

But even so, Defendants specifically objected to the requests regarding "internal audits" as vague and confusing because Plaintiffs failed to define that term. *See, e.g.*, Response to Request for Production No. 75: "This request is also vague and confusing as written with respect to the undefined term "internal audits." (*See* Pls.' Statement Pursuant to U.S.D.C., S.D. W. Va. L. R. 37.1(c).) Plaintiffs subsequently never defined the meaning of that term. Thus, to date, Plaintiffs have not formally requested a copy of Mr. Galea's assessment report, so the self-critical analysis privilege as to it has neither been asserted nor waived. At the very least, the facts surrounding the waiver issue would allow for the assertion of the privilege under *Ayers v.*

Continental Cas. Co., 240 F.R.D. 216 (N.D. W. Va. 2007) (elements to preclude automatic waiver of unasserted privilege set forth at Pls.' Mot. at 8.)

In addition to the report never having been requested, Defendants have been producing documents captured by the parties' agreed-upon search terms and those terms did not capture Mr. Galea's assessment report. (*See* Affidavit of Michael Anderton "Anderton Aff.", at ¶ 6, attached as Exh. C.) Indeed, the report does not even mention Digitek®, let alone any other product, and it is non-responsive to the parties' search terms. (Anderton Aff. at ¶¶ 5-6.)

In fact, the first time defense counsel even became aware of Mr. Galea's work during 2007 at Actavis Totowa, or of his assessment report, was during an initial pre-deposition interview on November 25, 2009. (Anderton Aff., at ¶ 2.) And as of the date of Mr. Galea's deposition, December 9, 2009, defense counsel had not yet seen the report. (*Id.* at ¶ 3.) It was not until December 18, 2009 that defense counsel received what was believed to be the assessment report, and that fact was not confirmed until January 6, 2009. (*Id.* at ¶ 4.)

B. The Self-Critical Analysis Privilege Applies to the Deposition Testimony and Assessment Report at Issue.

1. The privilege as defined in the Fourth Circuit.

Federal Rule of Evidence 501 leaves the area of privilege to a trial court's discretion. *Etienne v. Mitre Corp.*, 146 F.R.D. 145, 146 (E.D. Va. 1993). In enacting the Rule, Congress rejected the creation of specific privileges in favor of providing courts with greater flexibility. *Trammel v. United States*, 445 U.S. 40, 47 (1980); *Etienne*, 146 F.R.D. at 146. Rule 501 thus provides for development of privilege law on a "case-by-case basis." *Trammel*, 445 U.S. at 47; 1974 U.S.C.C.A.N. 7051, 7059 ("[T]he recognition of a privilege based on a confidential relationship and other privileges should be determined on a case-by-case basis.").

Courts in the Fourth Circuit addressing the self-critical analysis privilege have defined three criteria that must be met for the privilege to apply:

- First, the information contained in the document must result from an internal investigation or review conducted to evaluate or improve a party's procedures or products;
- Second, the party must originally have intended that the information remain confidential and demonstrate "a strong interest in preserving the free flow of the type of information sought"; and
- Third, the information contained in the documents "must be of a type whose flow would be curtailed if discovery were allowed."

Etienne, 146 F.R.D. at 147, *quoting Dowling v. American Hawaii Cruises, Inc*., 971 F.2d 423, 426 (9th Cir. 1992) (internal citation omitted); *accord Brem v. DeCarlo, Lyon, Hearn & Pazourek*, 162 F.R.D. 94, 101-102 (D. Md. 1995); *Deel v. Bank of America, NA*, 227 F.R.D. 456, 459 (W.D. Va. 2005).

The third criterion typically requires the court to "weigh the public interest served in preventing disclosure of confidential internal reviews against a plaintiff's need for the material to prove its case." *Etienne* at 147; *Brem*, 162 F.R.D. at 101-102. As the self-critical analysis privilege has developed over the years, "this balancing of public and private interests has become the essential consideration when a court decides whether the privilege should prevent disclosure of relevant information." *Id*. Thus, "the court must determine whether the type of internal review conducted by the party invoking the privilege is one that benefits the public interest and would be curtailed in the future if it were subject to disclosure during civil discovery." *Etienne* at 148; *Brem* at 101-102. Generally speaking, the privilege does not attach to underlying factual data, but does attach to all mental impressions, opinions, evaluations, recommendations, and theories based on that factual data. *Bradley v. Melroe Co.*, 141 F.R.D. 1 (D.D.C. 1992).

The seminal case on the adoption and application of the privilege is *Bredice v. Doctor's Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970); there, the court protected minutes and reports from hospital staff meetings concerning the death of plaintiff's decedent based on the "overwhelming public interest in the meetings of staff designed to review, analyze and evaluate clinical work of members for the purpose of continued improvement in care and treatment of patients." *Bredice*, 50 F.R.D. at 249. Specifically:

> Candid and conscientious evaluation of clinical practices is a sine qua non of adequate hospital care. To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations. *Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit.*

Bredice at 250.

Though there is no Fourth Circuit authority expressly adopting or rejecting the privilege, the federal district court in *Bradley v. Melroe Co., supra*, applied the privilege to investigative files of previous accidents involving the same allegedly defective seat bar interlock mechanism on which plaintiff based his claims. There, a loader operator injured due to an allegedly defective interlock mechanism brought claims against the loader manufacturer and moved to compel the production of in-house investigative files of previous accidents involving the same mechanism. In applying the self-critical analysis privilege, the district court held that the manufacturer could be required to produce all factual data contained in the files, but could redact all mental impressions, opinions, evaluations, recommendations, and theories. The investigative files of previous accidents were directed to the defendant's Product Safety Manager for the purpose of investigating an accident and to the defendant's chief engineer and designer of the interlock system to determine whether design changes were necessary. 141 F.R.D. at 1, 2.

The court noted that "manufacturers study reports of accidents involving their products for the purpose of ascertaining if preventative measures can be taken to avoid future accidents." *Id*. at 3: "The ultimate benefit to others from this critical analysis of the product or event far outweighs any benefits from disclosure. Valuable criticism could not be obtained under the threat of potential or possible public exposure for it is not realistic to expect candid expressions of opinion or suggested changes in policies, procedures or processes knowing that such statements or suggestions may very well be used against colleagues and employees in subsequent litigation." *Id*.

The same reasoning, however, does not apply to federally-mandated reports and studies, particularly in the context of discrimination cases: "Because such reports and studies are produced involuntarily, there is no reasonable expectation by the employer that such material will remain confidential. Moreover, . . . such [reports and studies] will hardly be curtailed in the future since they are mandated by law." *Etienne*, at 148; *see also Reynolds Metals Co. v. Rumsfeld*, 564 F.2d 663 (4th Cir. 1977) (distinguishing reports prepared solely for internal use – such as those in *Bredice* – in declining to apply the privilege to a government contractor's affirmative action programs and related information required to be furnished to the contracting agency); *Witten v. A.H. Smith & Co*., 100 F.R.D. 446 (D. Md. 1984), *aff'd*, 785 F.2d 306 (4th Cir. 1986) (distinguishing *Bredice*, and holding that self-critical analysis privilege did not protect affirmative action reports from discovery in a race discrimination suit); *accord McDougal-Wilson v. Goodyear Tire and Rubber Co.*, 232 F.R.D. 246 (E.D.N.C., 2005) (declining to apply privilege to affirmative action plans); *Deel v. Bank of America, NA*, 227 F.R.D. 456, 459 (W.D. Va. 2005) (declining to apply privilege to payroll practice audit performed not voluntarily, but in response to pending litigation).

2. The self-critical analysis privilege squarely applies to Mr. Galea's deposition testimony and assessment report.

Without question, Mr. Galea was tasked to perform an internal review of Actavis Totowa operations from a GMP perspective so that, ultimately, he could harmonize various aspects of Actavis Totowa GMP operations with GMP operations of other divisions or operating entities within Actavis on a global basis. (*See infra* at 2-4.) His assessment report reflects his observations and mental impressions of the Actavis Totowa facility from a GMP perspective. (Galea Aff. at ¶4.) Thus, the information contained in his report resulted from an "internal review" conducted to improve Actavis' GMP procedures globally, from a consistency standpoint. The first prong of the *Etienne* three-prong test has therefore been met.

Second, as established in Mr. Galea's Affidavit, he at all times intended that the information in his assessment report would remain confidential, by and between himself and the Actavis Group Quality Systems Department. (Galea Aff. at ¶ 5.) Though Plaintiffs argue that Mr. Galea "never suggested this his assessment was confidential" (Pls.' Mot. at 15), he was never asked.

As to the second part of prong two, there is, without question, a strong public interest in preserving the free flow of this type of information, particularly within a pharmaceutical company where candid evaluations to harmonize GMP practices relate directly to ensuring product safety, which in turn benefits the public health. Improvement within a pharmaceutical company to ensure consistent GMP practices, for the ultimate benefit of the public health, is exactly the type of information the self-critical analysis privilege was intended to protect. *Bredice*, *supra*. As in *Bredice*, "constructive professional criticism cannot occur in an atmosphere of apprehension" that Mr. Galea's observations of Actavis Totowa operations from a GMP consistency standpoint will "be used as a denunciation" of Actavis Totowa's 2007 GMP

practices in future product liability suits, as plaintiffs now attempt here. *Bredice*, at 250. The second prong of *Etienne* has therefore been met.

Last, the flow of this type of information would likely be curtailed if discovery were allowed. Mr. Galea's assignments were not federally-mandated; it was plainly a voluntary, internal assignment to achieve internal GMP consistency. While it is unlikely that pharmaceutical companies would no longer attempt to achieve GMP consistency in operations, it is likely that the discovery of this type of information will curtail the frank, constructive criticism of specific entity operations – necessarily required to achieve the desired result – for fear that such criticisms will be used against the company in subsequent litigation. *See, e.g., Bradley* at 3: "Valuable criticism could not be obtained under the threat of potential or possible public exposure for it is not realistic to expect candid expressions of opinion or suggested changes in policies, procedures or processes knowing that such statements or suggestions may very well be used against colleagues and employees in subsequent litigation." *Accord Witten*, *supra* at 453 (noting that the potential for frank criticism is more likely in the context of critiquing a fellow professional.)

As the *Etienne* and *Brem* Courts instruct, this third prong of the privilege typically requires the Court to "weigh the public interest served in preventing disclosure of confidential internal reviews against a plaintiff's need for the material to prove its case." *Etienne* at 147; *Brem*, 162 F.R.D. at 101-102. Here, Plaintiffs have no need for Mr. Galea's internal assessment report to prove their case; it does not even constitute the GMP compliance report they seek. This, balanced against the public interest in GMP consistency to ensure product safety, virtually mandates the privilege's protections under prong three.

Contrary to Plaintiffs' arguments, it is plain that Mr. Galea's assessment report does not constitute a "routine safety audit" prepared in the normal course of business. (Pls.' Mot. at 2, 6.) It was in fact an assignment made due to the recent acquisition of Actavis Totowa by Actavis Group in 2005 to assess the harmonization of GMP practices, and it was not a "safety audit" of any kind. (Galea Aff. at ¶¶ 3, 6-7.) For this reason, Plaintiffs' reliance on *Dowling v. American Hawaii Cruises, Inc*., 971 F.2d 423, 426 (9th Cir. 1992) is misplaced. (Pls.' Mot. at 6.) Likewise, the Northern District of Florida's decision in *Reichhold Chemicals, Inc. v. Textron, Inc*., 157 F.R.D. 522 (N.D. Fla. 1994) is inapposite (*id.*) – that case concerned application of the privilege to a retrospective analysis of an entity's compliance with federal environmental regulations.

The bulk of the remaining authority on which plaintiffs rely either concerns federally-mandated reports and studies or internal compliance audits – neither of which are at issue here – or involve the law of different states. (Pls.' Mot at 9-12.) While federal and state courts are indeed all over the map as to acceptance of the privilege, or the circumstances under which it may be applied, it is the law in this Circuit that applies to the issue before the Court. (PTO #31, Doc. 31, at 2, 3.) As noted above, Rule 501 provides for the development of privilege law on a "case-by-case basis." *Trammel*, 445 U.S. at 47. Under the facts set forth above, the privilege – as defined and applied under Fourth Circuit law – should apply to Mr. Galea's assessment report and deposition testimony.

C. Documents and Testimony Relating to Mr. Galea's General Assessment and Harmonization Visits Are Totally Irrelevant to Plaintiffs' Claims in this Litigation.

As a threshold matter, it is highly questionable that a general, broad-based GMP compliance audit – not directed toward any particular product – would be relevant in establishing a specific product defect in distributed Digitek®; that is a gap that no state's product liability

laws would find adequate to meet Plaintiffs' burden of proof. Moreover, this Court has already reigned in the scope of discovery in these cases to Digitek®, and its specific manufacturing processes and manufacturing history, with limited exception. (*See* PTO #27; affirmed, PTO #37.) Plaintiffs' last ditch fishing expedition has now gotten so far afield that Defendants fully expect that the scope of discovery issue will again be back before the Court in short order.

But a GMC compliance audit is not even what is in dispute here – the issue here is even further afield. As established above, Mr. Galea prepared a report about his general assessment of the recently-acquired Actavis Totowa LLC entity from a GMP perspective so that he could harmonize aspects of Actavis Totowa GMP operations with GMP operations of other divisions and operating entities within Actavis on a global basis. (Galea Aff. at ¶ 6.) Plaintiffs do not need this information to establish their claims; indeed it is entirely irrelevant to their claims. Any notion that Mr. Galea's assessment report meets Rule 402's relevancy requirements cannot be justified under the above facts.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2010, a copy of the foregoing **Actavis Defendants' Brief Opposing Plaintiffs' Motion to Compel Documents and Deposition Testimony** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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